UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,584	07/01/2003	Rajneesh Taneja	ABB01259P00350US (6950.US	5230

7590 09/14/2007

TAP Pharmaceutical Products, Inc.
Attention: Mark J. Buonaiuto
675 North Field Drive
Lake Forest, IL 60045

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,584	TANEJA, RAJNEESH	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks filed on 7/11/07 are acknowledged.

2. Claims 1-9 are included in the prosecution.

Response to Arguments

Rejection of claims 1, 2 and 5 under 35 USC § 102(a) and § 102(e) as being anticipated by WO 02/45692

3. Applicant's arguments with respect to the rejection of claims 1, 2 and 5 under 35 USC § 102(a) and § 102(e) as being anticipated by WO 02/45692 have been fully considered and are persuasive. The rejection of 3/14/07 is withdrawn.

Rejection of claims 1-9 under 35 USC § 103(a) as being unpatentable over WO 02/45692

4. Applicant's arguments with respect to the rejection of claims 1-9 under 35 USC § 103(a) as being unpatentable over WO 02/45692 have been fully considered and are persuasive. The rejection of 3/14/07 is withdrawn.

Rejection of claims 1-9 under 35 USC § 103(a) as being unpatentable over WO 94/25070 in view of WO 02/45692

5. Applicant's arguments with respect to the rejection of claims 1-9 under 35 USC § 103(a) as being unpatentable over WO 94/25070 in view of WO 02/45692 have been fully considered and are persuasive. The rejection of 3/14/07 is withdrawn.

6. However, upon further consideration, a new ground(s) of rejection is made in view of Depui et al. (US 6,183,776) and Depui et al. (US 6,183,776) in view of Phillips (US 2002/0045646).

Claim Objections

7. Claim 8 is objected to because of the following informalities: typo reciting: "viscosity of he" should be "viscosity of the". Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (US 6,183,776).

The claimed invention is a composition comprising (a) microgranules comprising a proton pump inhibitor coated with enteric coating; and (b) a liquid suspension vehicle having a pH less than 6.0 and having a viscosity sufficient to suspend the micro-granules.

Depui teaches an oral pharmaceutical dosage form comprising a proton pump inhibitor and an antacid agent or alginate. Depui teaches: "Some gastric acid suppressing agents, such as proton pump inhibitors, are susceptible to degradation/transformation in acid reacting and neutral media. In respect of the stability properties, it is obvious that one of the active substances being a proton pump inhibitor

must be protected from contact with acidic gastric juice by an enteric coating layer" (Col. 2, lines 45-51). A multiple unit tableted dosage form is disclosed "comprising enteric coating layered pellets of a proton pump inhibitor and antacid agent(s) also may be dispersed in a slightly acidic aqueous liquid and can be given to patients with swallowing disorders and in pediatrics. Such a suspension of dispersed units/pellets of appropriate size can be used for oral administration and also for feeding through a naso-gastric tube" (Col. 3, lines 56-63). Lansoprazole is disclosed as an example of a proton pump inhibitor (Col. 6, lines 10-20). The core material for individually enteric coating layered pellets is disclosed as seeds layered with proton pump inhibitor, and the size of the seeds "may vary between 0.1 and 2mm" (Col. 8, lines 35-50). The enteric coating is applied onto the core material. Enteric coating layer polymers are disclosed (Col. 10, lines 34-46). The enteric coating layered pellets comprising a proton pump inhibitor are compressed into a tableted dosage form (Col. 12, lines 1-6). "The multiple unit tablet preparation is also suitable for dispersion in an aqueous liquid with slightly acidic pH-value before being orally administered or fed through a naso-gastric tube" (Col. 13, lines 37-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the enterically coated layered pellets comprising a proton pump inhibitor and disperse them in a liquid suspension vehicle with a slightly acidic pH- as taught by Depui, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Depui teaches that a suspension of dispersed units/pellets of appropriate size can be

used for oral administration and also for feeding through a naso-gastric tube and can be given to patients with swallowing disorders and in pediatrics.

Regarding instant claim 1, the composition comprising microgranules with enterically coated proton pump inhibitor would have been obvious to one skilled in the art over the enterically coated layered pellets comprising a proton pump inhibitor taught by Depui. The limitation of the liquid suspension vehicle having a pH less than 6.0 would have been obvious to one skilled in the art over the tablet preparation taught by Depui that is also suitable for dispersion in an aqueous liquid with slightly acidic pH-value. The viscosity sufficient to suspend the micro-granules would have been obvious because prior to administration of the liquid formulation one skilled in the art would ensure that the proton pump inhibitor containing micro-granules were adequately suspended in the liquid and not settling out. One skilled in the art would modify the formulation in order to ensure the optimal viscosity to suspend the micro-granules prior to administration.

Regarding instant claim 2, the limitation of the micro-granules being between 100μm and 900μm would have been obvious to one skilled in the art over size of the seeds of the pellets, which vary between 0.1 and 2mm (or 100μm and 2000μm).

Regarding instant claim 3, the limitation of the viscosity of the composition being greater than 500cP would have been obvious to one skilled in the art over the dispersion in an aqueous liquid taught by Depui, because prior to administration of the liquid formulation one skilled in the art would ensure that the proton pump inhibitor containing micro-granules were adequately suspended in the liquid and not settling out.

One skilled in the art would modify the viscosity of the formulation in order to ensure the optimal viscosity to suspend the micro-granules prior to administration. The recited viscosity is an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 4, the lansoprazole would have been obvious to one skilled in the art over the lansoprazole as a proton pump inhibitor in the formulation disclosed by Depui.

Regarding instant claim 5, the method of treating a patient by providing a liquid suspension with suspended micro-granules of enterically coated proton pump inhibitor would have been obvious to one skilled in the art over the teaching by Depui that a suspension of dispersed units/pellets comprising a proton pump inhibitor of appropriate size can be used for oral administration and also for feeding through a naso-gastric tube.

10. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (US 6,183,776) in view of Phillips (US 2002/0045646).

The teaching of Depui is stated above.

Depui does not expressly teach a kit comprising a first container of micro-granules of enterically coated proton pump inhibitor and a second container comprising a liquid.

Phillips teaches that lansoprazole and other proton pump inhibitors are typically formulated in an enteric-coated solid dosage form (Page 1, [0004]). Phillips discloses

kits utilizing a dry dosage form for easy preparation of a liquid composition (Page 4, [0038]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the enterically coated layered pellets comprising a proton pump inhibitor and disperse them in a liquid suspension vehicle with a slightly acidic pH- as taught by Depui, and combine it with the kits utilizing a dry dosage form for easy preparation of a liquid composition, as suggested by Phillips, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the kits disclosed by Phillips ease mixing and administration. "A month's supply of powder or tablets, for example, can be packaged with a separate month's supply of diluent, and a re-usable plastic dosing cup" (Page 8, [0092]).

Regarding instant claim 6, the kit would have been obvious to one skilled in the art over the kit disclosed by Phillips.

Regarding instant claim 7, the lansoprazole would have been obvious to one skilled in the art over the lansoprazole as a proton pump inhibitor in the formulation disclosed by Depui.

Regarding instant claim 8, the limitation of the viscosity of the liquid being greater than 500cP would have been obvious to one skilled in the art over the dispersion in an aqueous liquid taught by Depui, because prior to administration of the liquid formulation one skilled in the art would ensure that the proton pump inhibitor containing micro-granules were adequately suspended in the liquid and not settling out.

Regarding instant claim 9, the limitation of the micro-granules being between 100μm and 900μm would have been obvious to one skilled in the art over size of the seeds of the pellets, which vary between 0.1 and 2mm (or 100μm and 2000μm).

Conclusion

11. Due to the new grounds of rejection, this action is made non-final.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600